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COVID-19

Evaluating and Testing Persons for Coronavirus Disease 2019

Centers for Disease Control and Prevention Adapted Guidelines https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html

Criteria to Guide Evaluation and Laboratory Testing for COVID-19

All health care providers, facilities and entities that offer testing shall make that testing available to people meeting testing criteria without regard to that person's ability to pay, type of health insurance, or participation in any particular provider network. Health care providers shall provide testing free of charge, including eliminating any cost sharing, co-payments or other direct-to-consumer costs.

Division of Public Health (DPH) requires that all commercial labs report all testing for SARS-CoV-2 immediately to the Division (via fax to 302-223-1540, email to reportdisease@delaware.gov, or 24-hour Office of Infectious Disease Epidemiology phone line at 1-888-295-5156). Further, all results should be shared with the Division immediately.

Clinicians considering testing of persons with possible COVID-19 should continue to work with the health department to coordinate testing through public health laboratories, or use COVID-19 diagnostic testing authorized by the Food and Drug Administration under an Emergency Use Authorization (EUA) through clinical laboratories. Increasing testing capacity will allow clinicians to consider COVID-19 testing for a wider group of symptomatic patients.

Clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Most patients with confirmed COVID-19 have developed fever¹ and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing).²

Other considerations that may guide testing are epidemiologic factors such as the occurrence of local community transmission of COVID-19 infections in a jurisdiction. Clinicians are strongly encouraged to test for other causes of respiratory illness.

Recommendations for Reporting, Testing, and Specimen Collection

Clinicians should immediately implement <u>recommended infection prevention and control</u> <u>practices</u> if a patient is suspected of having COVID-19. They should also notify infection control personnel at their health care facility and the health department if a patient is classified as a Person Under Investigation (PUI) for COVID-19.



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Testing may only be performed under the direction and order of an independently licensed medical practitioner (MD/DO, DMD/DDS, PA, or APRN).

There are multiple testing modalities. CDC recommends collecting and testing upper respiratory tract specimens (nasopharyngeal swab). Oropharyngeal swabs may be acceptable if nasopharyngeal supplies are exhausted. Specimens should be collected as soon as possible once a PUI is identified, regardless of the time of symptom onset.

Consistent with FDA guidance, the State of Delaware has identified point-of-care lateral flow immunoassays ("rapid tests") as useful diagnostic adjuncts for COVID-19 and subsequently developed guidance for use of these tests. Use of rapid tests is contingent upon implementation in appropriate clinical scenarios. Rapid testing may only be performed in accordance with Division of Public Health guidance on the use of rapid testing (https://coronavirus.delaware.gov/wp-content/uploads/sites/177/2020/04/RAPID-COVID-19-lgG-lgM-TESTING-GUIDANCE.pdf).

Only tests that have received an Emergency Use Authorization (EUA) from the FDA **OR** that have been independently verified by a CLIA certified laboratory may be used.

All testing must be performed in compliance with OSHA and CLIA regulations or if conducted in a clinical laboratory setting, in accordance with standards set forth by the Commission on Office Laboratory Accreditation (COLA).

All providers must provide each patient tested with educational materials developed by the Division of Public Health.

The ultimate implementation of, the clinical decision making from, and the reporting of COVID-19 testing, are the responsibilities of the licensed practitioner (MD/DO, DMD/DDS, PA, or APRN) who is listed as the ordering practitioner for the testing procedure.

Footnotes:

¹Fever may be subjective or confirmed.

²For healthcare personnel, testing may be considered if there has been exposure to a person with suspected COVID-19 without laboratory confirmation. Because of their often extensive and close contact with vulnerable patients in healthcare settings, even mild signs and symptoms (e.g., sore throat) of COVID-19 should be evaluated among potentially exposed healthcare personnel.